Are You Properly Equipped to Execute RISK-BASED SITE MONITORING?

As the life-science industry focuses on moving toward a risk-based site monitoring approach where partial source document verification (SDV) is employed, it is critical that the clinical organization have the right tools and processes in place to efficiently execute such a strategy. As is typical with the implementation of any new process, some sponsors and CROs have struggled with their initial venture into the new risk-based site monitoring paradigm. The specific reasons vary, but a key shortcoming is the lack of proper tools to support the planning and management of partial SDV.

Study teams call on their colleagues within biostatistics or IT to program study-specific algorithms that allocate each enrolled subject to a set of SDV requirements. Similar to the traditional approach of implementing subject randomization algorithms for a new study, these programming efforts are non-trivial and eat up precious resources and time during the critical study set-up phase. Another fall out of this approach is the lack of integration with the EDC tool that site monitors are using to perform and track their SDV activities. Reports or spreadsheets detailing the subject-by-subject and form-by-form SDV requirements must be periodically e-mailed to each site monitor, which they then must print out and reference continually while performing SDV. Add to this the realization that SDV progress and backlog cannot effectively be tracked — either by the site monitors or the broader study team — since SDV requirements are not in the same EDC system being used to track SDV completion. This lack of visibility makes it difficult for site monitors to plan and manage their workload, and for study managers to track progress and backlog.

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Given the high stakes involved **— both with patient safety and data quality —** it is crucial to choose the right systems to support SDV implementation.

So what should clinical R&D organizations and study teams do to avoid these pitfalls and ensure a more efficient, scalable, and successful partial SDV implementation? While having a well-defined strategy and process is always a critical element, it is also crucial to have the right tool-set. The following requirements provide a solid foundation to select the right tools to support your partial SDV strategy:

Integrated

Since EDC is the system in which SDV is performed and tracked, it is important that partial SDV plans be set up so that they can be managed directly within the EDC tool. This will allow site monitors to follow their natural SDV workflow without having to retrieve and reference separate reports containing the SDV requirements. It also provides for full visibility to the site monitor and study team on SDV progress and backlog, enabling more effective workload planning.

Auditable

An EDC-integrated approach should provide for full auditing of both the SDV plan and SDV completion within a single system.

Flexibility

The system should provide study teams with the ability to design and configure multiple SDV plans, both across studies and even within a single study. This includes a study-level plan, and the ability to define alternate plans that can override the study-level plan for individual sites or sites within a given geography.

Scalability

The system should allow for the design and configuration of study-specific partial SDV plans without the need for custom programming and validation efforts.

Choosing Correctly

Ease of use for site monitors is imperative for the successful adoption of partial SDV. Additionally, information gleaned from EDC and other eClinical repositories can be reviewed to identify potential quality issues at one or more sites, and this can be used to focus monitoring resources on those sites needing additional attention. This may include special visits to a site to review issues with them directly, and may call for increasing the SDV coverage at the site to ensure the requisite data quality.

Given the high stakes involved — both with patient safety and data quality — it is crucial to choose the right systems to support your partial SDV implementation. Incomplete and disjointed systems can seriously impede and even jeopardize your company's transition to the new risk-based monitoring paradigm. ■

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